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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,737	01/27/2006	Alexander Lucia Leonardus Duchateau	4662-21	9011
23117	7590	07/30/2007		
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER DAVIS, BRIAN J	
			ART UNIT	PAPER NUMBER
			1621	
			MAIL DATE	DELIVERY MODE
			07/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,737

Applicant(s)

DUCHATEAU ET AL.

Examiner

Brian J. Davis

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1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/26/05</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Information Disclosure Statement

The patent SE 8501132 has been lined-through where it appears under the Other Documents heading and properly listed instead under the Foreign Patent Documents section of the IDS.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For grammatical reasons, an unacceptable level of ambiguity is introduced into the claim language with respect to the proviso, since the proviso apparently repeats requiring that the carbonyl be the chiral compound when, if fact, from the preceding clause it appears that this already must be true.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by

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the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation "...at the α - or β -position...", and the claim also recites "...most preferably at the α -position...", which is the narrower statement of the range/limitation.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The proper dependency of claim 10 is unclear, since at present it depends from itself. Claims may depend only from preceding claims.

The remaining claims are also rejected under 35 USC 112, second paragraph, as claims which depend from indefinite claims are also indefinite. *Ex parte Cordova*, 10 USPQ 2d 1949, 1952 (PTO Bd. App. 1989).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 6, 8 and 14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by *Journal of Chromatography A* (1994), 664(2), p. 169-176.

The reference teaches the chromatographic separation (using a chiral stationary phase) of enantiomeric Schiff bases formed from the reaction of various aliphatic or aromatic 1,2-diamines with various benzaldehyde derivatives (page 170, Experimental section; page 173, Table 2; page 175, Conclusions section). The mixture of enantiomers is dissolved in methanol and eventually diluted with hexane prior to separation (page 170, Derivatization section).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4, 7, 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over by *Journal of Chromatography A* (1994), 664(2), p. 169-176.

Dependent claims 2, 4, 7, 13 and 16 further define the separation process of claim 1.

Journal of Chromatography A (1994), 664(2), p. 169-176, has been outlined above.

With respect to claim 2, applicant distinguishes over the prior art in that a mixture of diastereomers is separated. However one of ordinary skill in the art at the time of the invention would have immediately envisioned such a separation as obvious and been reasonably confident of its success given that the more difficult separation, that of enantiomers, can be accomplished according to the prior art.

With respect to claim 4, applicant distinguishes over the prior art in that SMB chromatography is taught rather than the HPLC of the prior art. However, one of ordinary skill in the art at the time of the invention would have recognized that the basic

technique – chiral chromatographic separation – could be extrapolated with a reasonable chance of success to other chiral chromatographic methodologies such as SMB chromatography.

With respect to claim 7, applicant distinguishes over the prior art in that the Schiff bases are hydrolyzed to yield the starting amine. However, one of ordinary skill in the art at the time of the invention would have immediately recognized the desirability of recovering the starting amine after separation given that the point of the prior art Schiff base separation is to develop a technique to separate and then recover the amines so that they can be used as intermediates for further reaction. (“Enantiopure diamines are important intermediates...” page 169, Introduction section, line 1).

With respect to claim 13, applicant distinguishes over the prior art in that a particular range of concentration of Schiff base mixture is taught. However, case law seems clear on this point: It is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ 33 (CCPA 1937). *In re Russell*, 439 F2d 1228, 169 USPQ 426 (CCPA 1971).

With respect to claim 16, applicant distinguishes over the prior art in that a racemization step and subsequent separation is taught. However, case law seems clear on this point: An additional racemization step in an otherwise known process is not a patentable modification. *Brenner v. Ladd*, 147 USPQ 87, 90 (DC 1965).

Allowable Subject Matter

The subject matter of claims 9-12 (assuming claim 10 properly depends from claim 9) would be allowable once the 112, second paragraph, rejections outlined above has been overcome.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: *Kexue Tongbao* (Foreign Language Edition) (1983), 28(11), p. 1574 (CAPLUS abstract) is cite to show a related resolution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached at 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 **BRIAN DAVIS**
PRIMARY EXAMINER

Brian J. Davis
July 23, 2007